

## 7. Peer Review Procedures

### 7.1 INTRODUCTION

To operate the WIPP as a repository for transuranic radioactive waste, the DOE must demonstrate that applicable health, safety, and environmental requirements have been satisfied. Peer reviews may be employed as part of a comprehensive quality assurance program. These peer reviews will give confidence that work completed, underway, or planned was, is, or will be properly performed. The ASME "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories," ASME-NQA-3-1989 Edition (NQA-3), includes peer review among those activities affecting quality associated with the collection of scientific and technical information, when other established methods cannot be used to establish the adequacy of information.

Additional peer review is also necessary to establish the validity of procedures, methods, or interpretations which may not be addressed by a quality assurance program. Because of the nature of the assessments at the WIPP, in particular the potential uncertainties associated with geotechnical data and their analyses, and the need to project performance over thousands of years, peer reviews are essential to assure that all important factors are considered in assessing the performance of the WIPP.

#### 7.1.1 Background

The 40 CFR part 194 compliance criteria for the WIPP provide the following requirements for peer review, at §194.27 of the final rule:

- (a) Any compliance application shall include documentation of peer review that has been conducted for, in a manner required by this section, for:
  - (1) Conceptual models selected and developed by the Department;
  - (2) Waste characterization analysis as required in §194.24(b); and
  - (3) Engineered barrier evaluation as required in §194.44.
- (b) Peer review processes required in paragraph (a) of this section, and conducted subsequent to the promulgation of this part, shall be conducted in a manner that is compatible with NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories."
- (c) Any compliance application shall:

- (1) Include information that demonstrates that peer review processes required in paragraph (a), and conducted prior to the implementation of the promulgation of this part, were conducted in accordance with an alternate process substantially equivalent in effect to NUREG-1297 and approved by the Administrator or the Administrator's authorized representative; and
- (2) Document any peer review processes conducted in addition to those required pursuant to paragraph (a) of this section. Such documentation shall include formal requests, from the Department to outside review groups or individuals, to review or comment on any information used to support compliance applications, and the responses from such groups or individuals.

The EPA must be satisfied that peer review processes at the WIPP are sufficient to assess the scientific premises properly on which the performance assessments are based.

## 7.2 OTHER PEER REVIEW PROGRAMS

### 7.2.1 Definition and Use of Peer Review

Peer review has a well-established role in controlling various aspects of scientific research, engineering research, scientific and engineering applications, and educational processes. Editors and publishers of technical journals use peer review to ascertain the quality and suitability of a manuscript submitted for publication. Funding agencies use peer review to seek advice concerning the quality and promise of proposals for research support. Some research institutions use peer review as another check on research in certain sensitive fields such as human experimentation.<sup>1</sup> Some universities use peer review for promotions of faculty (STE93).

Peer review serves a second objective of ensuring integrity in scientific research. Recent spectacular cases of fraud in scientific research have led to federal regulations that require

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<sup>1</sup> At the University of Michigan, potential researchers must complete a questionnaire that addresses certain key areas of concern, prior to submitting their project funding request. If the applicant indicates that the research will involve, for example, the use of human subjects, vertebrate animals, or radioactive materials, the University subjects the project funding request to one or more peer review committees for approval. These committees review the application for compliance with specific laws and regulations, why the research must be conducted in the manner proposed, and how the research will be supervised (UMI90).

At the University of Michigan, proposals for research on human subjects can be reviewed by as many as twelve peer review committees. The proposer must provide the rationale for and justify the use of each subject. This peer review process is designed by the University to compel the would-be researcher to think about their responsibilities, and to discuss these responsibilities with their colleagues (STE93).

peer review as a measure to detect and prevent continuation of these frauds (NAT93). The same pressures to enforce rules regarding misconduct in science have led to the inclusion of mandatory peer review for ongoing scientific and engineering research and development by government agencies.<sup>2</sup> For example, one study reported that in 1987, five cases of fraud and misconduct in science, primarily in biomedical research, were widely publicized. These cases galvanized the U.S. Congress to renew its earlier interest in regulating certain aspects of scientific research. In subsequent years, various federal agencies such as the Department of Health and Human Services (DHHS), and within DHHS, the Public Health Service and the National Institutes of Health (NIH), adopted rules to address these instances of fraud. One rule was specifically related to improving the performance of peer review (GOL93).

Many Federal agencies use some form of peer review to evaluate the technical merit of proposed research projects.<sup>3</sup> Similarly, private institutions frequently use peer review to evaluate research projects. Often the focus of these peer reviews is to determine which of several proposed research projects will be funded. Those projects which, through the peer review process, are deemed most promising are chosen for funding. Peer review is also used to determine if a particular project merits continued funding. Some Federal agencies use peer review to evaluate the technical adequacy of proposed or ongoing projects. This use of peer review most closely parallels the peer review process required by 40 CFR part 194.

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<sup>2</sup> See *e.g.*, 10 CFR Part 60

<sup>3</sup> The National Science Foundation (NSF) uses a merit review system to make major awards in support of important research facilities, centers, and other large-scale research-related activities. At the NSF, the entire process of determining which research projects are to be publicly funded is called the merit review system. The most important aspect of this merit review system is the technical peer review each potential research project receives. The merit review system encompasses the administrative procedures for conducting this peer review and the procedures for publicizing results (NSF94, 93, 92, 77; NSB67). Merit review also encompasses criteria that the NSF considers necessary to augment technical quality and competence. These criteria include immediate practical relevance, and the development of science and engineering capacity in all regions of the country (NSF94). The purpose of the review process is to ensure that the most meritorious projects are chosen for support, that the selection process is fair in practice and perception, and that the results in each case are clearly and publicly explained (NSF94; NAS93, 92). Officials at the NSF concluded that one of the reasons that the United States has the most successful research system in the world is because of the extensive use of peer review to identify the best ideas for financial support. According to NSF94, "Peer review-based procedures such as those in use at NSF, the National Institutes of Health, and other federal research agencies remain the best procedures known for ensuring the technical excellence of research projects that deserve public support. Motivating this process is clearly a true scientific interest in seeing that only technically feasible projects get funded (NSF94). However, fiscal realities, and a growing occurrence of dishonesty in the research process has focused even more attention on the adequacy of merit, or peer review at the National Science Foundation (NSF94).

## 7.2.2 Peer Review at the Department of Health and Human Services

### 7.2.2.1 Public Health Service

In the 1980s, the U.S. Congress began hearings on misconduct in scientific research because of highly publicized cases of outright fraud. These problems seemed to have occurred to a large degree in the biomedical research arena (GOL93). Congressional interest in this problem led to several attempts to reform control of research at government agencies staffed by the Public Health Service (PHS) (GOL93) and to require institutions receiving funding from U.S. government agencies to put in place measures to detect and correct misconduct in science (GOL93). In 1989, PHS promulgated a final rule which required any institution applying for funds from the PHS to certify that it had adopted satisfactory misconduct procedures. One element in this set of procedures was a strong peer review procedure (GOL93).

### 7.2.2.2 National Institutes of Health

Scientific research at the NIH is organized around Intramural and External projects, and the peer review process differs somewhat according to project designation.

**NIH Peer Review of Intramural Research.** Scientists in the Intramural Research Program of the NIH are generally responsible for conducting original research consonant with the goals of their individual Institutes, Centers, and Divisions. Senior NIH officials have expressed concern regarding the rigor of scientific research conducted by NIH scientists (NAT93). One of such research is peer review. In its 1990 "Guidelines for Conduct of Scientific Research at the National Institutes of Health," NIH officials define peer review and stress its importance as:

[an] expert critique of either a scientific treatise, such as an article prepared or submitted for publication, a research grant proposal, a clinical research protocol, or of an investigator's research program, as in a site visit. Peer review is an essential component of the conduct of science. Decisions on the funding of research proposals and on the publication of experimental results must be based on thorough, fair, and objective evaluations by recognized experts.<sup>4</sup>

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<sup>4</sup> See NAS93 quoting from "Guidelines for the Conduct of Research at the National Institutes of Health" NIH, 1990.

The guidelines go on to state the essential elements of the peer review process:

- the reviewer must be expert in the subject matter under review
- the reviewers should avoid any real or perceived conflict of interest that might arise because of a direct competitive, collaborative, or other close relationship with one or more of the authors of the material under review
- the review must be based solely on scientific evaluation of the material under review within the context of published information and should not be influenced by scientific information not publicly available
- the material being reviewed is privileged and should not be used to benefit the reviewer unless the information has previously been made public

Peer review is used at the NIH at all stages of research carried on under the control, direction, or funding of the organization. These stages are:

- idea/issue generation
- program formulation
- project proposal evaluation and selection
- final reports/other products review
- on-going program/project review

Peer review is performed to some extent in all these stages. There are, however, significant variations both in the extent and nature of the peer review, depending on the stage of research, and whether or not the activities are carried out by NIH employees, or if the activities are NIH-funded.

At the NIH, peer review is mandated by law. Peer review policy and practice are generally consistent throughout NIH with only limited variations among the institutes.

**NIH Peer Review of External Research.** Each institute of the NIH has a statutory peer review panel, called a National Advisory Council (NAC, or variation) that conducts analyses of projects. The NAC is usually composed of 16 to 18 senior level personnel, including a mix of scientific disciplines as well as mandatory representation by ex officio federal officials and public (i.e., nonscientific) members. The NACs have a broad charter to address any matter affecting the performance of their respective institute. All NACs prepare an annual report assessing broad issues related to their institute, including future directions and general policy.

These reports are then forwarded to the Director of NIH.

NACs participate in peer reviews at many stages of a project. The first stage is generally one involving the initial determination of project funding. Many different individuals and activities compete for funding from the various institutes. NAC participation is generally strong at this point in a potential project's life because the determination as to which projects are funded bears heavily upon the direction the institute will take in the future. NIH personnel need, and are statutorily required, to evaluate projects to ensure that only the most promising ones are funded. The early stages of a project in which the NACs are involved include:

- Idea/Issue Generation Stage — This is likely to be an initial policy determination or a determination to proceed along a certain avenue of research. Specific projects need not be addressed.
- Program Formulation Stage — This stage receives peer review similar to that in the Idea Generation stage. One aspect of the peer review process at this stage is to consider whether resource requirements related to long range goals are reflected in the peer advice described under the Idea Generation stage.
- Project Design — For external research activities, the peer review is generally limited. Following participation in the formulation of research programs, the NACs do not ordinarily play a part in the design of projects. According to one NIH official, this is in part because of time constraints on participation of council members. The limited review is also due to inadequate scientific expertise (in specialized areas of research) of NAC members, which as mentioned, include senior officials and members of the public, generally better qualified to provide broad ethical or legal reviews.
- Project Proposal Evaluation, Selection, and Award Stage — At this point a dual process of peer reviews takes place, looking at both technical merit and cost issues.

### 7.2.3 Peer Review at the National Aeronautics and Space Administration

The National Aeronautics and Space Administration (NASA) uses peer review primarily to evaluate the merit of research and development proposals, and to allocate funding (NAS87, 94). NASA also uses peer review to decide if certain projects warrant renewal or continued funding (NAS94). Organizationally, NASA includes three science offices and two

engineering offices,<sup>5</sup> each of which employs some form of peer review, particularly in regards to evaluating proposals for research and development. However, NASA's science offices use peer review to a much greater extent than do the engineering offices (NAS94). The explanation for this difference in use of peer review centers on the nature of work performed by the two types of offices. The engineering offices are more likely to engage in straight procurement actions, such as purchasing rocket engines, whereas the science offices have, as a goal, promoting specific types of research (NAS94). The discussion that follows primarily describes the peer review process followed by the science offices. The NASA engineering offices follow a similar, if somewhat truncated, version of the same process.

NASA uses two types of solicitations to obtain research proposals: an Announcement of Opportunity (AO); and a NASA Research Announcement (NRA). NASA uses Announcements of Opportunity for large research procurements such as designing an instrument for installation on a satellite. NASA uses Research Announcements for more narrowly focused scientific investigation, such as using data collected during the Magellan spacecraft voyage (NAS94).

Either solicitation is written to address certain hardware, policy, or scientific needs as envisioned by NASA. This narrow drafting of the solicitation eliminates the need to consider policy during subsequent peer reviews of the proposals (NAS94). NASA has relied primarily on panels convened under the auspices of the National Academy of Sciences (NAS) to advise the administration on scientific goals and priorities. The panels report to various boards. NAS creates these boards, excluding NASA scientists in order to avoid any possible conflict of interest. However, some panel members may be drawn from NASA offices (NAS94).

NASA takes the long-term science goals and priorities from the NAS and, through committees, translates these goals and priorities into programmatic goals and strategies. The committees are established by NASA under the auspices of an Advisory Council that is composed of about 20 distinguished individuals, including corporate executives, university

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<sup>5</sup> The three science offices are:

- Office of Life and Microgravity Sciences and Applications
- Office of Mission to Planet Earth
- Office of Space Science

The two engineering offices are:

- Office of Aeronautics
- Office of Advanced Concepts and Technology

scientists, historians, and others. NASA selects the members of the Advisory Council. Within the Advisory Council are a number of standing committees. These committees use the NAS goals and priorities to develop recommendations for major programs such as the Hubble space telescope (NAS94). These committees are, in effect, peer review panels.

When a NASA science office issues a research proposal (either an AO or a NRA), NASA scientists compete for proposal acceptance on the same grounds as outside, or external, scientists and external research entities such as universities. This intramural versus extramural competition does not exist for Announcements of Opportunity issued by one of the two NASA engineering offices, but may exist for NASA Research Announcements issued by the engineering office.

Once the NASA standing committees have recommended programs, NASA officials in the engineering and science offices translate them into specific program plans or projects, including budget proposals. Each program or project is assigned to a program office within the engineering or science office. At this point, the size of the program or project budget partly determines whether an Announcement of Opportunity or a NASA Research Announcement is made. The nature of the solicitation determines the following peer review process (NAS94).

NASA uses Announcements of Opportunity to solicit proposals from scientists in the United States and abroad. The AOs are typically used for larger budget items, about 100 million dollars (NAS94). In response to an AO, NASA may receive up to 100 proposals. The designated program scientist within a NASA science office establishes one or more peer review panels to review each proposal, and selects the members for each panel.

Approximately 50 to 75% of the peer review panel members are university scientists, with the remaining members from NASA or other government agencies. The proposals are mailed to the panel members for initial review. Some additional co-readers may also review the proposals and can add comments, but do not participate further in the evaluation process. After the initial review, the peer panel meets to discuss the proposals and reach consensus on the evaluations. At the conclusion of the panel deliberations, the peer panel submits its recommendations to the NASA program office. The recommendations are reviewed by

NASA staff, and a NASA Associate Administrator makes the final determination as to which proposals to fund (NAS94).<sup>6</sup>

NASA Research Announcements (NRAs) are usually for smaller-budget items and concern more narrowly focused scientific research. The NASA Program Manager determines the level of peer review to be conducted. Just as in an AO, the proposals are usually mailed to the members of the peer review panel. A follow-up panel meeting is often used to discuss the proposals and to make recommendations to the NASA program office. An award under an NRA will usually not call for a deliverable; rather, the expectation is that the results of the research will be published. In this manner, NASA officials feel they are advancing the boundaries of science (NAS94). Grants under the NRAs are typically for three years and the awards are in the \$100,000 range.

During the three-year period that an NRA is in effect, NASA conducts periodic (e.g., annual or mid-term) reviews of progress. This review is typically performed by the NASA Program Manager, and could result in termination of the NRA award. If the scientific research must extend beyond the original grant time period, the grantee submits a new proposal that is reviewed using the same process as followed for initial selection.

Periodic review of projects funded under an AO follows a somewhat different course. The initial peer panel that recommended particular grants will establish a Science Working Group composed, essentially, of all the principal investigators of the winning organizations. This Science Working Group is chaired by a NASA scientist. The Science Working Group meets periodically to review progress and the final deliverables.

#### 7.2.4 Peer Review at the U.S. Environmental Protection Agency

The EPA uses various panels such as Science Advisory Boards (SABs) (see Section 7.2.4.3) and the National Advisory Council on Environmental Policy and Technology (NACEPT) to advise the agency on scientific, technical, and policy matters. NACEPT activities are authorized under Public Law 92-563, the Federal Advisory Committee Act (FACA), and are

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<sup>6</sup> Note that a single AO could result in numerous contracts, each concerned with a specific aspect of the work described in the AO (NAS94). NASA awards under AOs typically call for production of specific hardware such as scientific instruments to emplace on a research satellite. As such, the award is controlled through a contract and the selection process is in many respects similar to a regular government procurement (NAS94).

designed to provide recommendations and advice to the EPA Administrator. Review and critique of documents and reports is a precursor to formulating sound advice.

The NACEPT is composed of several committees covering diverse technical areas. The EPA established the WIPP Subcommittee under the aegis of the Environmental Measurements and Chemical Accidents Committee to advise the Administrator in implementation of the WIPP Land Withdrawal Act (PL 102-579) (EPA93). Members of the WIPP Subcommittee include representatives from academia, an environmental activist organization, the New Mexico Environmental Evaluation Group, the State of New Mexico Environment Department, and various technical consulting companies. To date, the WIPP Subcommittee of the NACEPT has provided advice to EPA in three general areas:

- criteria to be used in evaluating DOE Test Phase Plan and Waste Retrieval Plan for WIPP
- criteria to be used in determining compliance with 40 CFR part 191
- selected issues related to 40 CFR part 194

The EPA uses SABs to provide advice concerning on-going scientific studies within the Agency. These SABs function in much the same manner as does the NACEPT. SAB members include personnel from inside and outside the agency.

Finally, EPA makes use of external peer review groups. These groups can be constituted as special panels formed by the agency, or can come from other government agencies. Examples of these reviews are provided in sections 7.2.4.1 through 7.2.4.3.

#### 7.2.4.1 Peer Review of Proposed Sewage Sludge Disposal Regulations

One particular EPA peer review effort concerned draft standards for the disposal of sewage sludge, U.S. EPA Proposed Rule 40 CFR parts 257 and 503. The proposed rule was reviewed by a peer review committee (PRC) created by an element of the U.S. Department of Agriculture (USDA).

The EPA, under authority of the Clean Water Act,<sup>7</sup> proposed regulations to protect the public

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<sup>7</sup> 33 U.S.C.A. 1251, *et. seq.*

health and the environment from any reasonably anticipated adverse effects of certain pollutants that might be present in sewage sludge. The proposed regulations were published in 1989, and included standards for the final use or disposal of sewage sludge applied to both agricultural and non-agricultural land, distributed or marketed, placed in disposal sites, or incinerated. Part of the proposed regulation asked the USDA to review the scientific and technical basis of the proposed rule. The review was conducted by a peer review committee created by USDA's Cooperative States Research Service (CSRS), Regional Research Technical Committee (W-170).<sup>8</sup> Dr. A.L. Page of the University of California, Riverside and Dr. T.J. Logan of Ohio State University were the co-chairs of the peer review committee. The rest of the peer review committee consisted of 33 experts from academia, government and private industry (USD89).<sup>9</sup>

The PRC met in Washington, D.C. for four days. The PRC broke into smaller workgroups centered around specific aspects of the proposed regulation. For example, workgroups analyzed those portions of the proposed regulations that dealt with monofills, with surface disposal, with agricultural land application, etc. Each workgroup reviewed the proposed regulations and prepared draft reports. During the four-day period, the entire 35-person PRC would meet to discuss progress and to identify common areas. After the four-day session, each workgroup reviewed and edited their section, and then the entire document was reviewed and edited by each of the PRC members. The two PRC co-chairs, along with the chairmen of each work group, met over a five-day period to revise and edit the complete draft report (USD89).

The PRC draft report is organized as a series of workgroup reports, with an overall summary and set of recommendations. The sections of the report prepared by the individual workgroups list the workgroup members, but do not show which workgroup member prepared any particular comment. The PRC draft report does not contain any information

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<sup>8</sup> The W-170 committee and its predecessors, W-124 and NC-118, are CSRS committees formulated for the purpose of conducting regional research. These regional research projects are developed by researchers from land grant universities, agricultural experiment stations, and USDA laboratories within four regions in the U.S. (USDA89). As is obvious by the peer review of 40 CFR Parts 257 and 503, the W-170 Committee engages in activities other than pure agricultural research.

<sup>9</sup> Four members of the PRC were from the EPA, the agency whose work was being reviewed (USD89). The PRC draft report does not explain how it avoided conflict of interest problems by having EPA personnel on the PRC staff. However, the breadth and detailed nature of the comments prepared by the PRC tend to indicate that the review was completely objective.

regarding the background or qualifications of individual PRC members, nor does it include any documentation regarding possible conflict of interest. In short, there is no way to know from reading the PRC report if there was any conflict of interest.<sup>10</sup>

#### 7.2.4.2 Ecological Risk Assessment Peer Review

In 1984, EPA organized the Risk Assessment Guidelines program to ensure scientific quality and technical consistency in the Agency's risk assessments. The first group of guidelines was issued in 1986, and focused on evaluating risks to human health. In 1991, EPA issued an agency-wide draft statement of general principles to guide ecological risk assessment. This guide was titled "Framework for Ecological Risk Assessment."

To improve the technical basis for ecological risk assessment guidelines, EPA requested an independent peer review of the draft "Framework for Ecological Risk Assessment." A panel of twenty experts participated in the review (EPA92).<sup>11</sup>

The peer review of the draft framework consisted of three steps. First, the draft framework document was mailed to each of the twenty members participating in the review. Each reviewer prepared comments that were in turn distributed to all other reviewers. Next, a peer review workshop was held to obtain an independent review of the logic, scientific validity, and utility of the principles that were proposed in the draft framework document. Workshop participants reached a consensus on the acceptability of some parts of the draft framework, and made recommendations for changes to other parts. Finally, a written report was prepared, summarizing the results of the workshop, and presenting the panel's recommendations to EPA (EPA92).

To help frame the discussion and focus attention on certain critical issues, each workshop participant was provided a set of "pre-meeting issue papers." These papers stated general

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<sup>10</sup> One other point that should be noted is that there is no indication of follow-up on any of the PRC draft report comments. While EPA may very well have incorporated all of the PRC comments into the proposed regulation, that fact was not evaluated in this analysis.

<sup>11</sup> Of the twenty participants, none were from the EPA, including its regional offices. Participants included members of state and federal agencies, private industry and (primarily) public and private universities (EPA92). Some of the entities represented had, however, done work for the EPA in the past. The EPA was represented by about 30 "observers" (EPA92).

issues and then requested that the participants comment on specific aspects of the risk assessment guidelines. For example, under the topic "Ecorisk Paradigm," each participant was presented with the following statement and question to consider: "The proposed paradigm for risk assessment is modeled after the National Research Council paradigm for human health risk [reference omitted]. Is the modified paradigm presented in the framework document appropriate for ecorisk assessments, or is another approach preferable?" (EPA92). This general issue was followed by several sub-issues and questions that addressed specific aspects of the proposed process for assessing risk.

The peer review described above did not indicate to what extent conflict of interest issues were considered, although as previously noted, the report did state that the peer review was "independent." The report also did not describe in detail the procedural steps followed throughout the peer review process. For example, there is no discussion about how the peer review members were selected, the process for incorporating comments, follow-up action if the authors of the draft framework document disagreed with any comments of the peer review team, etc.

#### 7.2.4.3 The Science Advisory Board

The EPA uses a number of advisory councils, often known as Science Advisory Boards (SABs), to provide guidance on a wide range of topics potentially affecting the environment (EPA92a). These boards are part of EPA's advisory committee program, and operate under the Federal Advisory Committee Act.<sup>12</sup> The EPA constitutes and terminates SABs as the need arises. For example, from 1992 to 1993, EPA formed eight new committees for topics as diverse as wood furniture manufacturing and local government policy, and terminated five committees (EPA93a).

The composition of some SABs indicate that their function extends beyond the technical arena. For example, the Clean Air Act Advisory committee comprises "50 senior representatives from state and local government, academic institutions, unions, environmental and public interest groups, industries and service groups." (EPA92a). The four workgroups

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<sup>12</sup> Public Law 92-463, October 6, 1972. Further guidance on the functioning of federal advisory committees can be found in General Services Administration Final Rule Subpart 101-6.10, "Federal Advisory Committee Management," August 1989.

formed from this committee addressed topics such as: effective communication/outreach methods for implementing reductions in airborne emissions; regulatory reform options; and alternative programs that would assist and encourage states to promote energy efficiency (EPA92a). On the other hand, the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel is comprised entirely of experts in the field of pesticides and the impact of their use on human health and the environment (EPA92a).

Each of the committees or SABs formed under EPA's advisory committee program develops or is issued a charter stating the purpose, objective and scope of activity, functions, and conduct of meetings (EPA92a). Committee members may or may not be compensated for their services depending on the individual committee. The EPA may pay travel and per diem expenses for all committee members. Some committee members may be government employees. All members are subject to conflict-of-interest restrictions (EPA92a).<sup>13</sup>

The various committees meet periodically throughout the year, at times established in their individual charters. The chair of each panel or committee submits a written report of the meeting. This report includes the panel's recommendations and conclusions. Transcripts are made and retained for the entire meeting (EPA92a).

#### 7.2.5 Nuclear Regulatory Commission Peer Review Guidance

Compliance criteria in 40 CFR part 194 require peer review at the WIPP to be performed in a manner compatible with NUREG-1297. NUREG-1297 contains a generic technical position for peer review at high-level nuclear waste repositories (NRC88). NUREG-1297 provides guidance on the definition of peer reviews, the areas where a peer review is appropriate, the acceptability of peers, and the conduct and documentation of a peer review.

The NUREG document defines the following peer review-related terms:

- Peer — a person having technical expertise in the subject matter, or a critical subset of the subject matter, at least equivalent to that needed for the original work.
- Peer review group — an assembly of peers representing an appropriate spectrum of

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<sup>13</sup> See 40 CFR Part 3, Subpart F - standards of Conduct for Special Government Employees. This regulation includes rules regarding conflict-of-interest. The rules require nominees to committees such as EPA's, to submit a Confidential Statement of Employment and Financial Interests (EPA Form 3120-1), that fully discloses any outside sources of financial support.

knowledge and experience in the subject matter. The group should vary in size based on the subject matter and the importance of that subject matter to safety or waste isolation.

- Peer review — a documented, critical review performed by peers who are independent of the work being reviewed. The review is an in-depth critique of the assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn from the original work.
- Peer independence — a peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed and, to the extent feasible, has sufficient freedom from funding considerations to assure the work is impartially reviewed.<sup>14</sup>

The NUREG document describes the circumstances under which a peer review is warranted. These circumstances occur when the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements cannot otherwise be established through: 1) testing; 2) alternative calculations; or 3) reference to previously established standards and practices. (These circumstances are the same as those listed in ASME NQA-3, previously described in section 7.1.) NUREG-1297 provides examples of these situations, including when:

- critical interpretations or decisions will be made in the face of significant uncertainty,
- decisions or interpretations having significant impact on PA conclusions will be made, or
- novel or beyond state-of-the-art testing, plans and procedures, or analyses are or will be utilized.

The composition of the peer review group depends on: the complexity of the work to be reviewed; its importance in establishing compliance with safety or performance goals; the degree of uncertainty in data or the technical approach; and the extent to which differing viewpoints exist. The peer review group should include individuals representing major schools of scientific thought. The actual number of peer reviewers is not as important as the technical qualifications of the reviewers. The group should be structured to avoid a bias

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<sup>14</sup> NUREG-1297 states that, because of the DOE's pervasive effort in the waste management area, most persons who would be acceptable from a technical perspective are likely to have had some connection to DOE in the past. As such, the NUREG document concludes that "[I]t may not be possible to exclude all DOE or DOE contractor personnel from participating in a peer review." (NRC88). The NUREG document suggests that in these cases, a documented rationale as to why someone of equivalent technical qualifications and greater independence was not selected should be filed with the peer review report (NRC88).

toward particular theories, methods of analysis, or institutional practices (NRC88). Each peer review group should be led by a chairman. In meetings and correspondence, the peer review group should evaluate and report on:

- validity of assumptions
- alternate interpretations
- uncertainty of results and consequences if wrong
- appropriateness and limitations of methodology and procedures
- adequacy of application
- accuracy of calculations
- validity of conclusions
- adequacy of requirements and criteria

NUREG-1297 states that full and frank discussions are essential between the peer reviewers and the persons who performed the work being reviewed (NRC88).

The peer review process should include written minutes of any proceedings, deliberations, and activities of the peer review group. After the peer review group completes its analysis, the agency responsible for quality assurance should produce a written report, under the direction of the peer review group chairman, and signed by each member of the group. The report should include statements by individual members stating any dissenting views or additional comments as appropriate. The report should also include information concerning the qualifications of individual peer review group members and their organizational affiliations (NRC88).

#### 7.2.6 Peer Review at the Department of Energy

The Office of Program Analysis (OPA) conducts peer review assessments of DOE research and development. "Procedures for Peer Review Assessments," DOE/ER-0491P, dated April 1991, describes general processes for conducting these peer reviews (DOE91). The peer review procedures are intended to provide the basis for implementing the methodology developed by OPA. The reviews are performed by examining individual projects which comprise a program and by assessing the quality of the research, quality of the research team, productivity, probability of success, and mission relevance for each project reviewed.

This OPA peer review is intended as a funding screening method, not a thorough scientific analysis of the project, or project report. In fact, this peer review procedure is also

limited—the review is limited to 65 minutes, and of that period, 30 minutes are allocated to the "Principal Investigator" to present the project's hypothesis, scientific approach, and results. After the peer review panel has completed all evaluations of all projects assigned to it for review, the panel members make their recommendations considering two basic criteria: the highest payoff research needs or opportunities, and their order of priority.

#### 7.2.6.1 Methodology

The DOE assembles peer review panels, as required, in its primary functional areas of research. Project reviews take place in panel sessions lasting from two to four days. Prior to the panel session, each principal investigator submits a package of documents which is distributed to the panel members to assist in evaluating the principal investigator's project at the panel session.

#### 7.2.6.2 Peer Review at the Yucca Mountain Site

Yucca Mountain is being considered as a site for long-term deposition of high-level radioactive waste. As such, many of the detailed geologic, hydrologic, and other scientific investigations being performed at the WIPP are or were also performed at Yucca Mountain. This section examines peer review of one of these proposed studies and one of the investigation reports.

Peer review panel members were provided advance copies of the draft documents to be considered. In one case, this was a copy of two proposals for in-situ study of radionuclide migration (NVO81). In the other case, the document was a report of an investigation of hydrology and geology in the Yucca Mountain area (NVO81a). Panel members were given a "charge," that is, they were asked by the Technical Project Officer to review the documents with certain criteria in mind. Following the panel session, each individual peer reviewer sent comments to the Technical Project Office. The technical project officer then prepared responses to these comments, and submitted the responses to NTS management.

**Peer Review of Radionuclide Migration in Tuff and Granite, NVO 196-23.** This review concerned two proposals for future in situ investigations of radionuclide migration in tuffaceous and granitic rock. The proposed radionuclide migration work was to be conducted by scientists from Los Alamos National Laboratory, Sandia National Laboratories, and Argonne National Laboratory for the tuffaceous rock and the Lawrence Livermore National

Laboratory for the granitic rock (NVO81).

Comments in the radionuclide migration peer review report were compiled from a peer review panel meeting conducted August 18-19, 1980 in Las Vegas, Nevada, as well as individual comments submitted by each of the peer review panel members. Individual comments were submitted after the panel meeting concluded, typically within one month (NVO81).

The need for a peer review panel was determined the Office of Nuclear Waste Isolation (ONWI) and the Nevada Nuclear Waste Storage Investigations (NNWSI).<sup>15</sup> Reviewers representing appropriate fields of expertise were invited to attend the review sessions. Nationally known, as well as prominent state and local, scientists were selected to participate in the peer review process. At the peer review meetings, the NNWSI Technical Project Officers, Principal Investigators from the laboratories, and NTS technical staff members involved in the radionuclide migration studies made detailed presentations and answered questions about their investigative actions and findings, as well as the proposed study efforts. The peer review panel consisted of eight scientists from universities, private industry, and a government agency other than DOE.<sup>16</sup>

The peer review report contains summarized comments from the panel sessions as well as individual comments from reviewers. Some summarized comments lack scientific precision. For example, in discussing the use of tracers, the peer review panel noted that "Tracers mentioned for cold experiment (except for U-235) will sorb like crazy and never be observed at the collection point...." (NVO81).

A section of the peer review report is a reply to the peer review comments prepared by the Technical Project Officer. The reply indicated that some of the panel's comments will be incorporated; however, the panel provided no mandatory comments, and there was no opportunity for the panel to concur with the reply prepared by the Technical Project Officer.

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<sup>15</sup> The NNWSI were a part of the National Waste Terminal (NWTs) Program of the DOE. The NNWSI were formally organized in 1977 and managed by the Waste Management Project Office of DOE's Nevada Operations Office. The NNWSI existed to develop or improve the technology for high-level nuclear waste handling, containment, and isolation, and determining whether suitable rock units on or adjacent to the Nevada Test Site (NTS) were technically acceptable for a licensed permanent nuclear waste repository (NVO81, NVO81a).

<sup>16</sup> The one government panel member was from the U.S. Geologic Survey.

**Peer Review of Geologic and Hydrologic Investigation of Yucca Mountain Peer Review Documentation, NVO-196-22.** This peer review was conducted in a somewhat different manner than the previously described review. Peer review panel members were provided the basic report ahead of time, and then met to discuss its technical merit. The panel session included a site visit to a portion of the Nevada Test Site. Following the panel session, individual members submitted written comments to the Technical Project Officer.

One reviewer felt that the panel meeting was not long enough to complete all required discussions. The same reviewer was dissatisfied with breaking the panel review into several different workshops. He felt that there was too much interrelationship between, for example, the hydrology and geology sections for them to be discussed separately.

Several panel members commented that, although the peer review panel presentations were generally useful, the panel members did not receive a handout of the material from the individual speakers prior to their discussions. One of these reviewers went on to note that "Most of us were not that familiar with the geologic formations, their positions in the geologic column, or the details that characterize them." (NVO81a).

The lone representative (out of ten) from industry noted that a certain difference existed between the academicians on the panel and himself.<sup>17</sup> Because of what he perceived as the "urgency of the problem" (i.e., finding a repository for high level radioactive waste), this reviewer felt that "more forward, goal oriented (industrial) approach to the depository siting should be considered." He urged inclusion of more industry representatives on future peer review panels. (NVO81a).

**Summary of NVO Peer Reviews.** These two peer review documents might seem, on cursory inspection, to be similar. However, NVO 196-23 appears to be related to a research/investigation funding decision while NVO 196-22 is more of a technical review that is intended to verify the adequacy of the investigation. However, the peer review comments in NVO 196-23 are primarily technical in nature, and contain no specific recommendations as to whether or not the two projects should be funded. The comments for NVO 196-22, on the other hand, address several programmatic issues in addition to technical comments.

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<sup>17</sup> According to this reviewer, "The university - industry differences in approach to applied research investigations is well known." (NVO81a).

The format for submitting comments, a general set of comments from the peer review panel followed by written comments from individual panel members, appears to have posed a dilemma for the NNWIS staff and the Technical Project Officer. Some individual comments were diametrically opposed, while other comments reflected the views of only one or a few members. One reason for this situation may have been the apparent lack of a panel chairman. Instead of the panel evaluating and concurring in the work, in effect several different (eight to ten) peer reviewers commented. The project staff was thus put in the position of having to respond to more comments than if a unified set of comments had been forwarded by a panel chairman, and the project staff had to respond to comments that did not always agree as to the direction the research should follow.

In addition, post-panel submission of written comments meant that any potential interactions between panel members and the project staff was necessarily limited or non-existent. This problem was apparent from several project staff replies. For example, several panel members referred to the need to access "open-file reports" and to have project documentation provided to the panel members in advance of the peer review panel meeting. The project team responded that they were uncertain as to what reviewers mean by higher profile reports. Misunderstandings like this might be resolved if the comments had been provided during the panel session, or if some mechanism existed for the panel members and the project staff to interact after submission of peer review comments.

### 7.3 SUMMARY OF PEER REVIEW

Peer review, as practiced at other government agencies and at private institutions such as universities, varies from an informal process in which reviewers are mailed a document and after review, simply send back a set of comments, to a more formal process with specific agendas, scheduled panel meetings, specific forms to use for recording comments, feedback mechanisms between panel members and project staff, etc. Based on the different processes used by various agencies for conducting peer reviews, the most effective peer reviews occur when:

- sufficient advance notice is given;
- adequate numbers of reviewers are selected so that all aspects of the project are represented;

- for large projects, a panel session lasts several days and includes site visits, if necessary;
- the panel has a chairman, and the chairman seeks to gain consensus on the peer review comments and presents a unified list of conclusions to the Principal Investigator;
- any strong disagreements among panel members are be highlighted;
- reviewers have a charter, or a check list of items or evaluation criteria, to consider in the review;
- members are not discouraged from voicing opinions in any area related to the subject being reviewed;
- a process is in place wherein responses to peer review comments are reviewed by at least the panel chairman;
- any major differences between panel and project staff are resolved;
- the agency forming the peer review panel strives for a balance of expertise, and of scientific views, on the panel.

Thus, use of peer review to establish the accuracy or adequacy of scientific procedures, methods, scope of examination, or data is best accomplished when peer reviewers are selected based on depth and area of expertise (and considering possible conflict of interest), and when the process and results are thoroughly documented and responded to by principle investigators.

After evaluating a variety of peer review programs for different purposes, EPA has identified important criteria for conducting and documenting peer review, as described above. The Agency determined that these criteria are clearly articulated in NUREG-1297, which provides appropriate guidance for implementing such procedures. Thus, the final rule provides that peer reviews required for the WIPP must be conducted in a manner that is compatible with NUREG-1297.

## 7.4 REFERENCES

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